Medasys Inc. Announces FDA Approval for Implantable Programmable Drug Pump

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Mount Olive, NJ, February 13, 2012 /PRNewsire/ -- Medasys Inc., a medical device company focused on providing implantable drug delivery solutions, announced today that it has received PMA approval from the U. S. Food and Drug Administration (FDA) for its Prometra® programmable implantable drug pump. Prometra will be the first non-peristaltic programmable implantable pump that has received FDA approval for delivery of INFUMORPH (preservative-free morphine sulfate sterile solution). INFUMORPH is indicated for intraspinal administration for the management of pain.

In addition to meeting all of the PMA safety and effectiveness requirements, a clinical trial demonstrated 97% clinical accuracy in the delivery of the physician-programmed dose, the highest labeled accuracy available for this type of pump.

"We are pleased to be able to utilize our engineering expertise and intellectual property to advance intrathecal therapy in the U.S.", Steve Adler, President and CEO of Medasys commented. "Prometra represents the first significant evolution in pump technology available in the US in over 15 years."

Advances in the Prometra pump design are intended to maximize device longevity and dose delivery accuracy. By reducing the number of moving parts and eliminating complex gears and rotors, pump dependability and reliability should be greatly improved. The Prometra also makes use of a patented valve gated precision dosing system to achieve extremely high accuracy, minimizing dose variations due to temperature, pressure, flow rate, or reservoir fill levels. It is expected that the combination of these factors will contribute to improved pain management.

It is estimated that 116 million people in the U.S. suffer with chronic pain. Continuous intrathecal delivery of INFUMORPH using a microinfusion device (e.g., implantable drug delivery pump) is a therapeutic option used for the management of chronic pain. Chronic pain can be debilitating, disabling, and negatively impact quality of life. The Prometra offers patients and physicians a new highly accurate option for drug delivery.

About Medasys

Medasys' strategic goal is to become the leading implantable drug delivery company in the world. Founded in 2005, Medasys received approval to conduct its first clinical trial in 2007 on the Prometra programmable implantable pump. Medasys received approval by the FDA to market the Prometra in 2012. Medasys has been granted multiple patents, and is focused on working closely with physicians to rapidly improve the capabilities of implantable drug delivery and management systems.

For more information see the Medasys web site at: http://www.MedasysPumps.com.

Forward-Looking Statements

This press release contains forward-looking statements. The Company wishes to caution the reader of this press release that actual results may differ from those discussed in the forward-looking statements and may be adversely affected by, among other things, reimbursement policies, commercialization of new technologies, intellectual property, and other factors.